PRODUCT DATA SHEET

VASCULAR



MAKOTO™ IMAGING SYSTEM AND DUALPRO™ IVUS+NIRS CATHETER

A DUAL-MODALITY INTRAVASCULAR IMAGING DEVICE

NIPRO

MAKOTO™ IMAGING SYSTEM AND DUALPRO™ IVUS+NIRS CATHETER

A dual-modality intravascular imaging device with the ability to assess vessel structure and plaque composition via IVUS imaging and Near-Infrared Spectroscopy (NIRS).

- Imaging system that uses ultrasound and near-infrared light to characterize plaque.
- An intravascular imaging device cleared by the FDA for the identification of patients and plaques at increased risk of MACE.
- The only dual modality intravascular imaging device on the market capable of detecting both plaque structure and composition using IVUS and NIRS
- 35-65 MHz extended bandwidth image gives a crisp HD-IVUS image quality to bring HD resolution and depth of penetration.
- Used before, during, and after PCI.

PRODUCT COMPLIANCE

- Complies with the following regulations:
  - — FDA
  - — KFDA
  - — MDR
  - — PMDA

CE 2797
Dualpro™ Sterile
Dualpro™ Class III
Makoto™ Class IIb

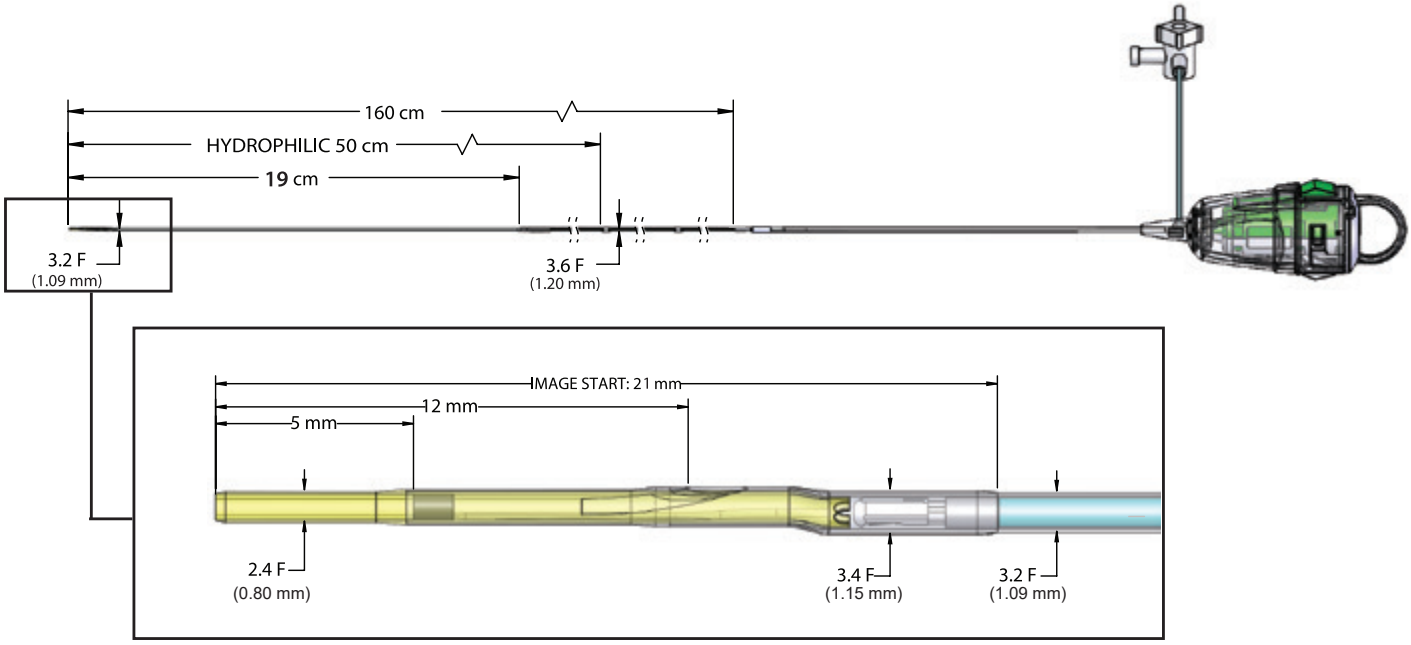
MANUFACTURING DETAILS

Legal manufacturer: Infraredx, A Nipro Company

Country of origin: USA

STERILIZATION AND SHELF LIFE

Sterilization	Single-use only	Shelf life
Ethylene Oxide STERILE EO		36 months





PRODUCT DETAILS

Dualpro™ IVUS+ NIRS Catheter, 35-65 MHz Rotational

Specifications

- IVUS Frequency Range: 35-65 MHz, 60% Bandwidth
- 160 cm Working Length
- 150 mm Imaging Range
- 16 mm Tip to IVUS Image Distance
- 16 mm IVUS Image Diameter
- 6 F Interventional Guide Compatible
- 0.014" Guide Wire Compatible
- 3.2 F Crossing Profile
- 3.4 F Tracking Reinforcement Sleeve (TRS) Outer Diameter

PRODUCT RANGE OVERVIEW

Product name : DUALPRO™ IVUS-NIRS IMAGING CATHETER, 3.2 F 35-65 MHZ, ETO,CE

Global product code
TVC-C195-42

EU ordering code	Asia ordering code
CATH-NI16-EU	IRX-TVC-C195-42-ECE



PRODUCT DETAILS

Makoto™ Intravascular Imaging System

Specifications

- IVUS Axial Resolution: 20 µm*
- **Pullback Speed:** 0.5, 1.0, 2.0 mm/s, 1800 rpm
- **Live IVUS Speeds:** 0.0, 2.0, 10.0 mm/s, Bi-directional, 960 rpm

PRODUCT RANGE OVERVIEW

Product name : MAKOTO™ NIRS/IVUS CONSOLE

Global product code
TVC-MC10

EU ordering code	Asia ordering code
MC10-MKTCNSL-UU	IRX-TVC-MC10-CE

Languages

14 languages on the IFU

English (EN), Czech (CS), German (DE), French (FR), Dutch (NL), Spanish (ES), Italian (IT), Korean (KO), Japanese (JP), Danish (DA), Latvian (LV), Norwegian (NO), Slovak (SK), Swedish (SV)

* Theoretical resolution based on transducer design, data on file

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